

RESPONSE TO RESTRICTION REQUIREMENT

U.S. Appln. No. 09/786,319

B4 of cells in response to an antigen comprising the step of contacting the culture with an amount effective to down regulate the activity of said antigen presenting cell of Zot in combination with said antigen, said amount effective to down regulate the activity of said antigen presenting cell.

REMARKS

On page 2 of the Office Action, the Examiner issues a Restriction Requirement under 35 U.S.C. § 121 to one of the inventions of the following groups:

Group I - Claims 1-25, drawn to methods of using Zot; or

Group II - Claims 1-25, drawn to methods of using Zonulin.

Specifically, the Examiner states that since Zot and Zonulin are distinct proteins, they do have a single general inventive concept and lack unity of invention.

Applicants hereby elect the invention of Group I, i.e. use of Zot without traverse.

Further, Applicants hereby amend the claims to limit such to the elected invention without prejudice or disclaimer to pursue the non-elected subject matter in a Divisional Application.

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The Examiner is invited to contact the undersigned at his Washington telephone number on any questions which might arise.

Respectfully submitted,

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A P P E N D I X

Marked-Up Version of Changes

IN THE TITLE:

The title is being amended as follows:

"METHOD OF USING ZOT [OR ZONULIN] TO INHIBIT LYMPHOCYTE PROLIFERATION IN AN ANTIGEN-SPECIFIC MANNER".

IN THE CLAIMS:

The claims are being amended as follows:

Claim 1. (Amended) A method of suppressing antigen presenting cell-mediated lymphocyte proliferation in a mammalian host pre-exposed to a particular antigen comprising the step of administering to said host an effective amount of [a Zot-related immunoregulator selected from the group consisting of] Zot [or zonulin], said amount effective to down-regulate the activity of said antigen presenting cell.

Claim 2. (Amended) A method of suppressing antigen presenting cell-mediated lymphocyte proliferation to a particular antigen in a mammalian host comprising the step of administering to said host an effective amount of [a Zot-related immunoregulator selected from the group consisting of] Zot [or zonulin] in combination with said particular antigen, said amount effective to down-regulate the activity of said antigen presenting cell.

Claim 3. (Amended) A method of treating a mammalian host afflicted with an auto-immune or immune-related disorder or disease comprising the step of administering to said host an effective amount of [a Zot-related immunoregulator selected from the group consisting of] Zot [or zonulin], said amount effective

to down-regulate antigen presenting cell-mediated lymphocyte proliferation.

Claim 4. (Amended) A method of treating a mammalian host afflicted with an auto-immune or immune-related disorder or disease comprising the step of administering to said host an effective amount of [a Zot-related immunoregulator selected from the group consisting of] Zot [or zonulin] in combination with an antigen specific to said disease or disorder, said amount effective to down-regulate antigen presenting cell-mediated lymphocyte proliferation.

Claim 5. (Amended) A method of treating of a mammalian host suffering from immune rejection subsequent to tissue or organ transplantation comprising the step of administering to said host an effective amount of [a Zot-related immunoregulator selected from the group consisting of] Zot [or zonulin], said amount effective to down-regulate antigen presenting cell-mediated lymphocyte proliferation.

Claim 6. (Amended) A method of treating a mammalian host suffering from immune rejection subsequent to tissue or organ transplantation comprising the step of administering to said host an effective amount of [a Zot-related immunoregulator selected from the group consisting of] Zot [or zonulin] in combination with a specific transplantation antigen, said amount effective to down-regulate antigen presenting cell-mediated lymphocyte proliferation.

Claim 7. (Amended) A method of treating a mammalian host afflicted with an inflammatory or allergic diseases or disorders comprising the step of administering an effective of [a Zot-related immunoregulator selected from the group consisting

of] Zot [or zonulin], said amount effective to down-regulate antigen presenting cell-mediated lymphocyte proliferation.

Claim 8. (Amended) A method for the treatment of a mammalian host afflicted with an inflammatory or allergic diseases or disorders comprising the step of administering an effective of [a Zot-related immunoregulator selected from the group consisting of] Zot [or zonulin] in combination with a specific inflammatory related antigen or allergen, said amount effective to down-regulate antigen presenting cell-mediated lymphocyte proliferation.

Claim 13. (Amended) The method of Claims 1 to 8, wherein said [immunoregulator] Zot is administered in admixture with at least one of the group consisting of a pharmaceutically acceptable carrier, adjuvant and delivery vehicle.

Claim 15. (Amended) The method of Claim 2, 4, 6 or 8, wherein said antigen and said [immunoregulator] Zot are concomitantly or sequentially administered.

Claim 16. (Amended) The method of Claims 1 to 8, wherein said [immunoregulator] Zot is administered to a mucosal surface.

Claim 17. (Amended) The method of Claim 2, 4, 6 or 8 wherein said antigen and said [immunoregulator] Zot are administered to a mucosal surface.

Claim 20. (Amended) The method of Claims 1 to 8, wherein said [immunoregulator] Zot is administered parenterally.

Claim 21. (Amended) The method of Claim 2, 4, 6 or 8, wherein said antigen and said [immunoregulator] Zot are administered parenterally.

Claim 22. (Amended) The method of Claims 1 to 8, wherein the mode of administering said [immunoregulator] Zot is selected

from the group consisting of intravenous, intradermal, intramuscular, and subcutaneous.

Claim 23. (Amended) The method of Claim 2, 4, 6 or 8, wherein the mode of administering said antigen and said [immunoregulator] Zot is selected from the group consisting of intravenous, intradermal, intramuscular, and subcutaneous.

Claim 24. (Amended) A method of suppressing antigen presenting cell-mediated lymphocyte proliferation in a culture of cells pre-exposed to a particular antigen comprising the step of contacting the culture with an amount of [a Zot-related immunoregulator selected from the group consisting of] Zot [or zonulin], said amount effective to down regulate the activity of said antigen presenting cell.

Claim 25. (Amended) A method of suppressing antigen presenting cell-mediated lymphocyte proliferation in a culture of cells in response to an antigen comprising the step of contacting the culture with an amount effective to down regulate the activity of said antigen presenting cell of [a Zot-related immunoregulator selected from the group consisting of] Zot [or zonulin] in combination with said antigen, said amount effective to down regulate the activity of said antigen presenting cell.